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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,030	12/12/2003	Vahid C. Saadat	USGINZ02513	3503

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EXAMINER	
LANG, AMY T	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
05/16/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,030	SAADAT ET AL.	
	Examiner	Art Unit	
	AMY LANG	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-29,32-35 and 40-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-29, 32-35, and 40-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/09/2011 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. **Claims 26-29, 32-35, and 40-49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (US 2002/0111534 A1) in view of Cerier (US 2004/0133238 A1) and Jaffe (US 2002/0161281 A1).

With regard to **claims 26 and 45**, Suzuki et al. (hereinafter Suzuki) discloses an apparatus for performing a medical procedure within a hollow body organ (see entire document). The device comprises an overtube (84) and a first catheter (14) inserted through the overtube (Figures 1 and 3; [0038]; [0039]). It is the examiner's position that a user is able to manually steer the distal end of the overtube so that the overtube comprises a steerable distal region. As shown in Figures 1 and 12, the first catheter comprises a flexible tube and a distal tissue engaging assembly with jaws (17a, 17b) ([0039]). The tissue engaging assembly grabs a patient's tissue to form a first tissue contact point (Figure 13).

Suzuki further discloses a flexible delivery catheter (42) comprising an internal lumen through which a needle (44) is inserted ([0044]; Figure 8). Initially, the flexible delivery catheter is inserted into the patient parallel to the first catheter, a direction that is aligned with a longitudinal axis of the proximal portion of the flexible delivery catheter ([0054]). A distal portion of the flexible delivery catheter is then bent toward the first tissue contact point ([0054]; Figure 17). It is the examiner's position that the bending produces a bent catheter that is generally transverse to the longitudinal axis of the proximal portion of the catheter. The needle is then slidably extended out of the distal end of the flexible delivery catheter and through the tissue ([0055]; Figure 17).

Therefore, the needle, which was previously retained within bending section, now extends from a distal end of the bending section of the flexible delivery catheter.

If applicant were to argue that the bending of the flexible delivery catheter does not produce a bend that is generally transverse to the longitudinal axis, is the examiner position that the delivery catheter of Suzuki is adapted to bend substantially ninety degrees. This would allow the needle to produce a clean cut while traversing through the tissue.

As shown in Figure 1, the bending section of the flexible delivery catheter (42) is attached and connected to tissue engaging assembly (17a, 17b) through first catheter (14) and overtube (84). The instant claims merely recite a connection and are not limited to a direct connection.

Once the needle is deployed through the tissue, as shown in Figure 17, a suture (46) on suture retaining device (50) is utilized to secure a tissue fold produced at the first tissue contact point ([0058]). Therefore, the flexible delivery catheter and suture retaining device work together to deliver an anchor, suture (36), and secure a tissue fold and therefore together overlap the instantly claimed anchor delivery assembly.

Although Suzuki teaches the suture as disposed through a lumen of the needle and pressed in the needle to exit out from the distal end of the needle, Suzuki does not specifically teach a push rod to push the suture out from the distal end of the needle ([0058]).

Cerier also discloses an apparatus for performing medical procedures within a hollow body organ (see entire document). As shown in Figure 10, the apparatus

comprises a needle (54 or 56) through which a suture is disposed ([0047]-[0049]). The suture is attached to securing elements (14, 16) which are pushed out the distal end of the needle by push rod (62) ([0049]). Since the suture also exits out the distal end of the needle, the push rod acts upon the suture. Therefore, Cerier teaches wherein it is well known in the art for a hollow needle to comprise a push rod to push a suture, or at least an anchor, out the distal end of the needle. This advantageously allows the suture to be properly deployed from the needle at the designated time. Since Suzuki teaches wherein the suture is deployed through the needle and Cerier teaches an advantageous method to properly deploy the suture, it would have been obvious to one of ordinary skill in the art at the time of the invention for the apparatus of Suzuki to further comprise a push rod within the needle lumen.

Furthermore, Suzuki does not specifically disclose the guide tube as having a flexible state and a rigid state and a steering wire that provides a steering capability to the distal region of the overtube.

Jaffe discloses an overtube, guide tube (14), designed to facilitate insertion of an endoscope through a tortuous pathway ([0002]). The guide tube is slideably disposed over the catheter and comprises a flexible and rigid state (Figure 1; [0028]; [0037]; [0038]). As shown in Figure 3, tensioning elements (30) transition the overtube between the flexible and rigid states ([0041]). Therefore, tensioning elements (30) clearly overlap the instantly claimed mechanism. It the examiner's position that the tensioning elements are configured to be manipulated from outside a patient's body.

Since the overtube of Jaffe advantageously facilitates insertion of an endoscope through an internal passageway, it would have been obvious to one of ordinary skill at the time of the invention for Suzuki to utilize the overtube of Jaffe.

Additionally, Jaffe teaches the distal end of the guide tube can be controlled through a steering capability to provide an optimal pathway through the patient ([0044]). Tensioning elements (30) are also disclosed as steering the distal end of the overtube by causing it to "flex into different position" ([0044]) and therefore overlap the instantly claimed steering wires. Since Jaffe teaches multiple tensioning elements (30A, 30B, 30C, and 30D), it is the examiner's position that, for instance, tensioning elements 30A and 30B overlap the instantly claimed steering wires and tensioning elements 30C and 30D overlap the instantly claimed mechanism to transition the overtube.

With regard to **claims 27-29**, Jaffe teaches wherein tensioning elements (30) are placed circumferentially about the overtube to control the transition from a flexible to rigid state or vice versa. The tensioning elements may be manipulated individually, so that only one portion of the overtube is transitioned ([0041]). For instance, as shown in Figure 3 of Jaffe, when only tensioning element 30C is manipulated, only that side of the overtube would transition from a flexible to a rigid state or vice versa. The side of the overtube that tensioning element 30D runs would not transition, so that only one section of the overtube remains in a flexible or rigid state while another section is manipulated and transitioned to the opposite state.

With regard to **claim 32**, as shown in Figure 17 of Suzuki, the needle contacts the tissue at a location proximal of the first tissue contact point.

With regard to **claim 33**, it is also the examiner's position that each jaw member (17a, 17b) of Suzuki touches the tissue to form a first and second tissue contact point. As shown in Figure 17, the first tissue contact point is proximal of the second tissue contact point. Slider handle (23) manipulates the jaw members and therefore overlaps the instantly claimed tissue approximation device.

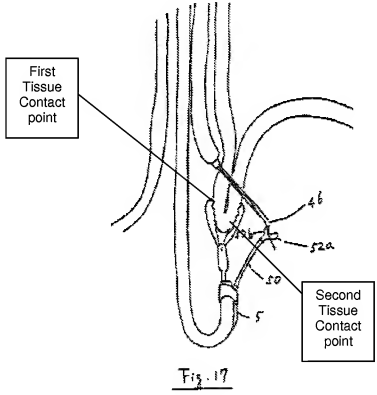

Fig. 17

With regard to **claims 34 and 35**, Suzuki merely discloses two catheters inserted within an overtube (Figure 1). Therefore, it is the examiner's position that it would have been obvious at the time of the invention to flip the device so that the first catheter lies

above the flexible delivery catheter. This entry angle would be advantageous while attempting to access various anatomical parts. Therefore, the tissue grabbing assembly would contact the tissue to form first and third contact points. The needle would produce a second tissue contact point and the first tissue contact point would be proximal of the third tissue contact point. Additionally, all three tissue contact points would be linearly displaced.

With regard to **claims 41-44**, the apparatus disclosed by Suzuki in view of Jaffe is configured to engage mucosa, musclaris, or serosa.

With regard to **claims 40, 46, and 49**, the anchor, suture (46) is configured to be delivered through the needle (44) since the suture is inserted in the needle ([0058]).

With regard to **claims 47 and 48**, Suzuki further discloses endoscope (2 or 6) movably disposed within the overtube ([0038]).

Response to Arguments

5. Applicant's arguments filed 02/09/2011 have been fully considered but they are not persuasive. Applicant argues that Suzuki does not teach the flexible delivery catheter as connected to the tissue engaging assembly of the first catheter. However, the claims only recite a connection and are not limited to a direct connection through a hinge assembly. As discussed above, the flexible delivery catheter of Suzuki is indirectly attached to the tissue engaging assembly.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

05/12/2011
/AMY LANG/
Examiner, Art Unit 3731